

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

DIANNE D. DAHL,

Plaintiff,

v.

Civil Action No. 2:12-cv-6944

C. R. BARD, INC.,

Defendant.

**MEMORANDUM OPINION AND ORDER**

Pending before the court are all remaining pretrial motions. All are ripe for adjudication.

**I. Background**

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse (“POP”) and stress urinary incontinence (“SUI”). In the seven MDLs, there are more than 58,000 cases currently pending, approximately 7,000 of which are in the Bard MDL, MDL 2187. In an effort to efficiently and effectively manage this MDL, I decided to conduct pretrial discovery and motions practice on an individualized basis so that once a case is trial-ready (that is, after the court has ruled on all *Daubert* motions and summary judgment motions, among other things), it can then be promptly transferred or remanded to the appropriate district for trial. To this

end, I ordered the plaintiffs and defendant to each select 50 cases, which would then become part of a “wave” of cases to be prepared for trial and, if necessary, remanded. *See* Pretrial Order (“PTO”) # 102, No. 2:10-md-2187 [ECF No. 729]. This selection process was completed twice, creating two waves of 100 cases, Wave 1 and Wave 2. Thereafter, I entered orders on subsequent waves. Ms. Dahl’s case was selected as a Wave 2 case by the plaintiffs. PTO # 118, No. 2:10-md-2187 [ECF No. 841].

## **II. Legal Standards**

### **a. Summary Judgment**

To obtain summary judgment, “the movant must show that there is no genuine dispute as to any material fact and that the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). In turn, to avoid summary judgment, the nonmovant must offer some “concrete evidence from which a reasonable juror could return a verdict” in his or her favor. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 256 (1986).

### **b. Choice of Law**

Under 28 U.S.C. § 1407, this court has authority to rule on pretrial motions in MDL cases. To determine the applicable state law for a dispositive motion, the court generally refers to the choice-of-law rules of the jurisdiction where the plaintiff first filed her claim. *See In re Air Disaster at Ramstein Air Base, Ger.*, 81 F.3d 570, 576 (5th Cir. 1996); *In re Air Crash Disaster Near Chi., Ill.*, 644 F.2d 594, 610 (7th Cir. 1981); *In re Digitek Prods. Liab. Litig.*, MDL No. 2:08-md-01968, 2010 WL 2102330, at \*7 (S.D. W. Va. May 25, 2010).

This case was originally filed in the United States District Court for the District of Minnesota. Therefore, I use Minnesota's choice-of-law rules to determine which state's law to apply to this case. The parties agree, as does the court, that these principles compel application of Wisconsin law to the plaintiff's claims. Minnesota focuses on two factors in resolving choice-of-law issues: (1) the maintenance of interstate order and (2) the advancement of the forum state's interest. *See In re Baycol Prods. Litig.*, 218 F.R.D. 197, 207 (D. Minn. 2003) (stating that only two factors in Minnesota's usual five-factor test apply to the resolution of choice-of-law issues arising under tort law) (citing *Nodak Mut. Ins. Co. v. Am. Family Mut. Ins. Co.*, 604 N.W.2d 91, 94–96 (Minn. 2000)). With respect to the first factor, the court should look to the state with “the most significant contacts with the facts relevant to the litigation.” *Id.* Here, that state is Wisconsin, where the plaintiff resides and underwent implantation surgery. The second factor, which requires the court to consider “the state law in which the plaintiff lives and in which the injury occurred,” also weighs in favor of applying Wisconsin law. *See, e.g., In re Baycol*, 218 F.R.D. at 207 (“[A]s the injury occurred in the state of plaintiff's residence, the substantive law of the state of plaintiff's residence should be applied to their claims.”); *Foster v. St. Jude Med., Inc.*, 229 F.R.D. 599, 605 (D. Minn. 2005) (“[P]roper consideration of Minnesota's choice-of-law factors reveals that the law of the state where the [d]evice was implanted would apply to Plaintiffs' [products liability] claims.”). Accordingly, Wisconsin substantive law governs this case.

### **c. Daubert Motions – Specific Causation**

Expert testimony is admissible if the expert is qualified and if his or her expert testimony is reliable and relevant. Fed. R. Evid. 702; *see also Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). An expert may be qualified to offer expert testimony based on his or her “knowledge, skill, experience, training, or education.” Fed. R. Evid. 702.

In the context of specific causation expert opinions, the Fourth Circuit has held that “a reliable differential diagnosis provides a valid foundation for an expert opinion.” *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 262–63 (4th Cir. 1999). “A differential diagnosis that fails to take serious account of other potential causes may be so lacking that it cannot provide a reliable basis for an opinion on causation.” *Id.* at 265. However, an expert’s causation opinions will not be excluded “because he or she has failed to rule out every possible alternative cause of a plaintiff’s illness.” *Id.* At bottom, the court has broad discretion to determine whether expert testimony should be admitted or excluded. *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 200 (4th Cir. 2001).

### III. Discussion

#### a. Bard’s Motion for Summary Judgment [ECF No. 41]

Bard’s Motion for Summary Judgment [ECF No. 41] is **GRANTED in part** as to the following conceded claims: manufacturing defect.

For reasons appearing to the court, Bard’s Motion for Summary Judgment [ECF No. 41] is also **GRANTED in part** as to the following claims: negligent inspection, marketing, packaging, and selling. Under Wisconsin law, a negligence

action requires the proof of four elements: “(1) A duty of care on the part of the defendant; (2) a breach of that duty; (3) a causal connection between the conduct and the injury; and (4) an actual loss or damage as a result of the injury.” *Rockweit v. Senecal*, 541 N.W.2d 742, 747 (Wis. 1995). “The duty of any person is the obligation of due care to refrain from any act which will cause foreseeable harm to others even though the nature of that harm and the identity of the harmed person or harmed interest is unknown at the time of the act.” *Id.* After it is shown that a duty of care was owed, “the plaintiff is simply required to prove that the defendant failed to exercise ordinary care and the act or omission complained of was the cause, in the legal sense, of the plaintiff’s injury.” *Greiten v. LaDow*, 235 N.W.2d 677, 685 (Wis. 1975).

Bard contends that the plaintiff’s claims for negligent inspection, packaging, marketing, and selling of the Align fail for lack of evidence. The plaintiff, in response, argues that there is ample evidence that demonstrates Bard breached a duty to the plaintiffs and that there was resulting harm from this breach. The plaintiff states that Bard was negligent in failing to include adequate warnings, failing to include appropriate instructions for use, exaggerating the benefits of the product, and marketing and selling the product without adequate testing. However, apart from reciting allegations that form the plaintiff’s failure to warn and design defect claims, the plaintiff does not offer any support that Bard breached a legal duty that caused the plaintiff’s injuries in its “inspection, marketing, labeling, packaging, or selling” of the Align. Accordingly, Bard’s Motion on these points is **GRANTED**.

After considering the parties' proffered arguments and evidence, I **FIND** that genuine disputes of material fact exist regarding the plaintiff's remaining claims. Accordingly, to the extent Bard's Motion challenges any other claims, the Motion is **DENIED**.

**b. Bard's Motion for Partial Summary Judgment [ECF No. 43]**

The question of whether a plaintiff is entitled to punitive damages often involves an interlocking web of factual determinations respecting the defendant's conduct. The evidentiary record is frequently muddled enough on the point that genuine issues of material fact remain. That is the case here. Consequently, Bard is not, at least at this stage of the case, entitled to judgment as a matter of law on the punitive damages claim. Thus, the Motion for Partial Summary Judgment [ECF No. 43] is **DENIED**.

**c. Specific Causation Daubert Motions [ECF Nos. 45, 47, 49, 51, 53, 55, 58, 59, 60, 63, 64, 65, 66, 67, 70, 72, 73, 75, 77, 79, 81, 83, 85, 89, 91, 93, 95, 145, 146, 147, 148, 149, 150, 151, 152, 153, 154, 155, 178]**

Many of the *Daubert* motions filed in this MDL raise the same or similar objections. One particular issue has been a staple in this litigation, so I find it best to discuss it in connection with every expert. I have repeatedly excluded evidence regarding the FDA's section 510(k) clearance process in these MDLs, and will continue to do so in these cases, a position that has been affirmed by the Fourth Circuit. *In re C. R. Bard, Inc.*, 81 F.3d 913, 921–23 (4th Cir. 2016) (upholding the determination that the probative value of evidence related to section 510(k) was

substantially outweighed by its possible prejudicial impact under Rule 403). Because the section 510(k) clearance process does not speak directly to safety and efficacy, it is of negligible probative value. *See id.* at 920 (“[T]he clear weight of persuasive and controlling authority favors a finding that the 510(k) procedure is of little or no evidentiary value.”). Delving into complex and lengthy testimony about regulatory compliance could inflate the perceived importance of compliance and lead jurors “to erroneously conclude that regulatory compliance proved safety.” *Id.* at 922. Accordingly, expert testimony related to the section 510(k) process, including subsequent enforcement actions and discussion of the information the defendant did or did not submit in its section 510(k) application, is **EXCLUDED**. For the same reasons, opinions about the defendant’s compliance with or violation of the FDA’s labeling and adverse event reporting regulations are **EXCLUDED**. In addition to representing inappropriate legal conclusions, such testimony is not helpful to the jury in determining the facts at issue in these cases and runs the risk of misleading the jury and confusing the issues. Insofar as any *Daubert* motion in this case challenges the FDA-related testimony discussed here, the motions are **GRANTED**.

The parties have identified more experts than can ever be called in a trial of any reasonable length. In this case alone, the parties have filed thirty-nine separate *Daubert* motions. Thus, I have considered principles of good judicial efficiency and proper management of judicial resources, and I now determine that substantive rulings on these motions are better suited for cases that will actually be tried on the merits. Accordingly, all remaining *Daubert* challenges to expert testimony in this

case are **RESERVED** for trial.

**d. The plaintiff's Motion to Strike [ECF No. 156]**

For reasons appearing to the court, the plaintiff's Motion to Strike [ECF No. 156] is **DENIED as moot**.

**IV. Conclusion**

The court **ORDERS** that:

- Bard's Motion for Summary Judgment [ECF No. 41] is **GRANTED in part** and **DENIED in part**;
- Bard's Motion for Partial Summary Judgment [ECF No. 43] is **DENIED**;
- The specific causation Motions [ECF Nos. 45, 47, 49, 51, 53, 55, 58, 59, 60, 63, 64, 65, 66, 67, 70, 72, 73, 75, 77, 79, 81, 83, 85, 89, 91, 93, 95, 145, 146, 147, 148, 149, 150, 151, 152, 153, 154, 155, 178], to the extent that the parties seek relief that is consistent with this Memorandum Opinion & Order, are **GRANTED in part**. In all other respects, the court **ORDERS** that the parties' motions are **RESERVED in part**; and
- The plaintiff's Motion to Strike [ECF No. 156] is **DENIED as moot**.

The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: March 21, 2017



